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09/913,643	10/19/2001	Mika Jokinen	TUR -115	4103

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed 11/09/05.

The claims presented in response to the final rejection, which are claims 16, 18, 19 and 24-34, are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 11/09/05 has been entered.

The claims:

Claims 28 and 29 are claims directed to method of administering biologically active agent to a human or animal; the method comprises implanting or injecting or mucosally attaching the delivery device of claim 30 where the fiber comprises active agent.

Claims 34, 16, 18 and 19 are directed to method for preparing biodegradable silica fiber, the method comprises correlating a desired biodegradability of a silica fiber with a viscosity of a silica sol, preparing the silica sol and spinning the fiber from said sol; and the spinning process begins when the viscosity of the silica sol reaches a value correlating to said desired biodegradability of the silica fiber (claim 34). Claims 16, 18 and 19 depend from claim 34 and further define the method.

Claims 30-33 and 24-27 are directed to controllably biodegradable silica fiber that has a solubility of 0.2 to 20 wt%/hr and the fiber is spun from silica sol, biodegradation rate of the

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fiber is adjusted by controlling the viscosity of the starting point of the spinning (claim 30) or adjusting the biodegradation rate of the fiber by controlling the viscosity of the spinning sol (claim 32).

The composition claims are product by process claims and “ product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.” And “[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). (MPEP 2113 [R-1].

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 34, 16, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. Claim 34 directly correlating biodegradability of a silica fiber with viscosity of a silica sol, and there is no exemplification showing how that is done. The Figures, specifically Figures 8, 10 and 12 provide variation of dissolution as a function of viscosity.

5. Claims 34, 16, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear how the viscosity is correlated with the biodegradation. Correlating biodegradability with viscosity is examined as correlating dissolution with starting viscosity of the sol.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Ahola et al. (WO 97/45367).

Ahola discloses preparation of biodegradable silica-xerogel fibers by drawing the fibers from silica sol prepared by sol-gel process; the start of the drawing process was found to be approximately 10 mPas (Example 2).

Claim 34 is generic to preparation of silica fiber. Ahola clearly discloses preparing silica sol, spinning the fiber from the silica sol and the spinning begins at a determined viscosity of the sol. The silica fiber of Ahola is biodegradable and dissolved in simulated body fluid. Since Ahola starts the spinning process at a specified viscosity, a determination was made to spin the sol at a specific viscosity. Therefore, Ahola meets the limitations of the claim.

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8. Claims 34, 16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US 4,919,871).

Lin discloses method of preparing silica fibers by preparing a sol, ageing the sol until a desired spinning viscosity is reached and the sol is then drawn into fibers (Example 1; column 2, lines 19-56). The sol is aged to a room temperature viscosity of 129 poise (12900 mPas) in Example XII and this viscosity meets the viscosity limitations of claims 16, 18 and 19. The disclosure that the sol is aged to a desired spinning viscosity reads on determination of spinning viscosity that would produce the desired fiber.

It is noted that Lin was previously applied as art against cancelled claims and as such was withdrawn in the final rejection. However, upon further review and consideration, it is noted that claim 34 is directed to spinning a sol into fibers at a predetermine viscosity. There is no data in applicants' specification where viscosity is correlated with biodegradability. Figures 8, 10 and 12 of applicants' specification describe the relationship of solubility rate as a function of viscosity and does not state biodegradability as a function of viscosity.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 34, 16, 18 and 19 and 24-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Peltola et al. (US 6,632,412).

Peltola prepares silica fiber by determining a spinning viscosity, preparing a sol, ageing the sol to the desired viscosity of 2000 cp (2000mPas) and then drawing the fiber from the sol (column 2, lines 23-27). Peltola further discloses the effect of ageing, heat treatment on the bioactivity and solubility of the fiber (column 6, line 65 to column 8 line 67). FIB 1 (B) shows a

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dissolution rate of 0.4, 0.7, 1.3 wt%/hr at 2 weeks, 3 months and 5 months of ageing respectively, FIB 2 (B) shows a dissolution rate of 0.4, 0.8, 1.4 wt%/hr at 2 weeks, 3 months and 5 months of ageing respectively, and FIB 1 (C) shows a dissolution rate of 2.8, 5.8, 8.5 wt%/hr at 2 weeks, 3 months and 5 months of ageing respectively (Table II) and claimed dissolution rates read on these values. Peltola's silica fiber can be implanted as a device for delivering growth factors, anti-inflammatory agents, anti-microbial agents and tranquilizing agent (abstract; column 2, lines 19-22, 36 and 39; column 3, lines 53-66).

As noted in MPEP 2112.01 [R-3], II, "products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. In the alternate, claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. (WO 97/45367). Claims 16, 18 and 19 are included in this rejection.

As discussed above, Ahola starts drawing the fibers from the sol at a specified viscosity of 10 mPas. Ahola does not specifically state the viscosity is correlated with biodegradability of the fiber and it is from such a correlation that the start viscosity for the spinning process is determined at 10 mPas. However, since the fiber of Ahola is controllably dissolvable, it stands to reason that a certain start viscosity is necessary before the sol can be spun. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to spin the silica sol according to Ahola. One having ordinary skill in the art would have been motivated to spin the sol at a start viscosity to produce dissolvable fiber.

Regarding claims 16, 18 and 19, which are directed to the viscosity at which the spinning begins, it is noted that the disclosed start viscosity of 10 mPas is significantly less than the start viscosity of 10,000 to 100,000 mPas. While the claimed and disclosed viscosities are different, there is no further data showing the reasons for the difference, for example, the claims have not recited concentration of the silica sol that would yield a viscosity of the type recited. The prior art does not indicate the concentration of the sol that would give disclosed viscosity. There is also no demonstration that the claimed viscosity provides unexpected results to the spun fiber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to start the spinning at 10 mPas as the viscosity predetermined for the spinning. One

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having ordinary skill in the art would have been motivated to spin the sol at a viscosity that would be expected to yield a fiber having the desired dissolution.

12. In the alternate, claims 34, 16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US 4,919,871).

As discussed above, Lin's method of preparing fibers comprises ageing the sol to a desired spinning viscosity. While Lin does not specifically describe correlating start viscosity with biodegradability, Lin clearly discloses ageing the sol to a desired spinning viscosity at which viscosity the spinning process may begin. Therefore, one having ordinary skill in the art would have been motivated to determine a viscosity at which spinning would start to produce the desired fiber.

13. Claims 30-33 and 24-29 (i.e. 24-33) are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. (WO 97/45367).

Ahola is discussed above. In Example 2, the spinning started at viscosity 10 mPas, the fibers were dissolved (page 14, lines 6-8) in simulated body fluid (23 °C and pH of 7.54; 37 °C and pH of 7.40); this section does not disclose the dissolution rate. In lines 18-20 at page 14, Ahola discloses that the fibers kept at room temperature dissolved "at significant amounts," and that 10-weight% of the room temperature fibers stored in a desiccator dissolved within 4 weeks. Furthermore, in vivo dissolution test conducted on rats by implanting silica fibers showed that the fibers have been integrated into the surrounding connective tissues after two weeks of the implantation (page 14, line 27 to page 15 line 18). Ahola also discloses that the fibers can be used as delivery devices that can be implanted or injected or attached to mucosa of human or animal body to deliver any of the drugs listed on page 6, lines 11-37 (page 4, line 32 to page 6

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line 37). The disclosure of the fiber containing drugs read on claims 24-27 and the disclosure that the fiber containing the bioactive agent(s) can be implanted or injected or attached to the mucosa of human or animal reads on claims 28 and 29.

However, Ahola does not disclose the claimed dissolution rate of 0.2 to 20 wt%/h. A complete or near complete dissolution of implanted fiber was observed 2 weeks after implantation. A desiccated fiber dissolved at a rate of 10 wt%/4 weeks. Ahola fails to disclose the mg-amount of the fiber upon which the dissolution was conducted. There is also no demonstration in applicants' specification that the rate of dissolution provides unusual results to the delivery device of the claims. Both the claimed fiber and the fiber of the prior art dissolve and deliver bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the fiber of Ahola. One having ordinary skill in the art has the technical know how to determine the rate of dissolution of the fiber implanted in the rat. In the absence of factual evidence, the claimed dissolution rate is not patentable over the prior art fiber that dissolves after 2 weeks of implantation.

14. Claims 16, 18, 19 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 196 09 51, English translation provided by applicants. The DE reference discloses viscosity of 0.05-50 Pas (50-50,000 mPas) and a preferred viscosity of 0.5 to 2 Pa (500 to 2,000 mPas) (page 7, last 2 lines of the last paragraph). This viscosity range lies within the claimed viscosity range 1,000 to 100,000 mPas and thus meets the limitations of claims 16, 18 and 19. Claim 34 does not recite the starting viscosity. The DE reference discloses that the degradation rate of the fibers can be adjusted to the requirements of each purpose of use and that the fibers degrade under condition prevailing in the human organism and specifically dissolve in body-like

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fluids (second full paragraph of page 3; 4th full paragraph of page 4) and this meets the limitation of simulated body fluid. The DE reference further discloses that the fiber dissolves/degrades at 10-100 nm fiber radius per day and a fiber having a radius of 10 μm completely dissolves in 50-500 days (4th full paragraph of page 4).

Regarding correlation of biodegradability with viscosity, it is noted that, to the extent that biodegradability is synonymous with dissolution, the correlation of dissolution with viscosity reads on starting the spinning process at a predetermined sol viscosity to produce the desired fiber having desired dissolution.

The prior art discusses dissolution in terms of radius of the fiber/day. The claimed invention discusses dissolution in terms of wt%/hr. The radius of fiber/day dissolved can be converted to radius of fiber/hr by the person of ordinary skill or the skilled artisan. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was to prepare silica fiber according to the DE reference. One having ordinary skill in the art would be motivated to prepare the fiber of the DE reference with the expectation that a fiber having a radius of 10 mm would dissolve/degrade within 50-500 days. One having ordinary skill in the art would have the technical know how to determine the degradation/dissolution rate in wt%/day or wt%/h and to adjust the degradation rate according to the desired use as suggested by the DE reference. In the absence of factual evidence the claimed dissolution rate does not patentably distinguish the fiber of the prior art having dissolution rate in radius/day, which can be converted to radius/h.

15. Claims 34, 16, 18 and 19 are rejected under 35 U.S.C. 102(e) as anticipated by Peltola et al. (US 6,632,412) as discussed above under 35 USC 102(e) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Peltola et al. (US 6,632,412).

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Peltola is discussed above. Peltola does not specifically state that the dissolution of the fiber is correlated with the viscosity of the sol at the start point. Peltola however discloses that the starting point of the spinning step corresponds to a solution viscosity of at least 2,000 cP (2,000 mPas) (claim 1); that ageing of the sol influences the viscosity of the sol and the dissolution of the fiber (column 5, line 53 to column 6 line 52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and age sol according to Peltola. One having ordinary skill in the art would have been motivated to age the sol at a time duration required to provide a sol viscosity at which the spinning of the sol would be expected to provide silica fiber having the desired dissolution.

Applicants' argument:

Regarding Ahola,

a) Ahola does not show correlation of biodegradability and viscosity as is shown in Figures 8, 10 and 12 of applicants' specification

b) Ahola does not disclose a solubility of 0.2 to 20 wt%/h in simulated body fluid and that Ahola discloses that the room temperature fibers stored for four months dissolved by 10 wt% within four weeks

16. Applicants' arguments filed 11/09/2005 have been fully considered but they are not persuasive.

a) The figures referred to by applicants, Figures 8, 10 and 12 failed to show any correlation of biodegradability and viscosity.

b) Applicants' claimed rate of dissolution is determined using 10 mg fiber without regard to the time of ageing while the mg amount of fiber that Ahola reports the dissolution on for the 4

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weeks is not known and Ahola desiccates the fiber for months. There is no factual evidence showing that the 10 mg of Ahola's fiber treated as the 10 mg of applicants' fiber fails to show applicants' dissolution or that equal amounts of the fiber of the prior art and the claimed fiber, which are treated the same do not show the claimed dissolution profile. As noted in MPEP 2112.01 [R-3], II, "products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The correlation step referred to in claim 6 of 6,922,580 is a definite reference to specific data, not hypothetical reference and claim 6 is a dependent claim. The correlation while being a positive step reads on deciding to spin the fiber after the sol has reached a specific viscosity keeping in mind that no specific viscosity value is claimed in claim 34.

Regarding DE 196 09 551,

c) The DE reference fails to state correlation of biodegradability with viscosity

d) The DE reference fails to disclose a fiber having a solubility rate of 0.1 to 20 wt%/hr and the fiber of the DE reference dissolves in 50 days as opposed to 21 days for the inventive fiber.

17. Applicants' arguments filed 11/09/05 have been fully considered but they are not persuasive.

a) The DE reference discloses that the degradation rate of the fibers can be adjusted to the requirements of each purpose of use and that the fibers degrade under condition prevailing in the human organism and specifically dissolve in body-like fluids (second full paragraph of page 3; 4th full paragraph of page 4) and this meets the limitation of simulated body fluid. The DE reference further discloses that the fiber dissolves/degrades at 10-100 nm fiber radius per day and a fiber having a radius of 10 μ m completely dissolves in 50-500 days (4th full paragraph of page 4). Figures 8, 10 and 12 in applicants' specification, failed to show any correlation of biodegradability and viscosity.

b) The dissolution of the fiber within 50 days is not the same as dissolution of applicants' fiber in 21 days since the mg amounts of the prior art fiber and the mg amount of the inventive fiber that dissolved within 21 days is not declared. The dissolution rate recited in the claims pays no regard to the ageing process. There is no factual evidence showing that same 10 mg-amounts of the DE fiber and the inventive fibers show different dissolution rates when tested under the same conditions and environmental effects or that equal amounts of the fiber of the prior art and the claimed fiber, which are treated the same do not show the claimed dissolution profile.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Blessing Fubara
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A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name and title.